Comparison of CDPH Guidelines and CIRM Regulations
Regarding iPSC Research and SCRO Committee Review Requirements

CDPH Guidelines for HSCR	CIRM Regulations	Differences/Considerations for Committee Review
§2(e) "Covered stem cell line" means a culture-derived, *human pluripotent stem cell population derived from an embryo or product of SCNT* that is capable of: 1) sustained propagation in culture; and (2) self-renewal to produce daughter cells with equivalent developmental potential.	§100020(c) "Covered stem cell line" means a culture-derived, *human pluripotent stem cell population* that is capable of 1) sustained propagation in culture; and (2) self-renewal to produce daughter cells with equivalent developmental potential. This definition *includes both embryonic and non-embryonic human stem cell lines* regardless of the tissue of origin.	-CDPH revised definition to exclude most research involving iPSC -CIRM retains definition to include iPSC research

§5(a) Research involving the *procurement or use of human oocytes* as part of human stem cell research…	§100070(a) CIRM-funded research involving the procurement or use of human oocytes *or the creation of human gametes* may not commence without SCRO Committee review and approval…	-CDPH: "procurement or use of human oocytes"
		-CIRM includes above and "or the creation of human gametes"
		• Should Guidelines be revised to match CIRM language?
		  ○ Pro: consistency w/ CIRM
		  ○ Con: would likely fall under iPSC research until materials are planned for use in creating embryos/cell lines/etc.
		  ○ From women's reproductive health standpoint, procurement of oocytes needs special protections while creating gametes doesn't raise same concerns

§5(b) Covered research involving *use of human embryos*…	§100070(b) CIRM-funded research involving *procurement, creation or use of human blastocysts or embryos* may not commence without SCRO Committee review and approval…	-CDPH: "use of human embryos" -CIRM: "procurement, creation or use of human blastocysts and embryos" • Should Guidelines be revised to match CIRM language?
§5(c) Covered research with the aim to derive or create a covered stem cell line…		
§5(d) Clinical trials involving the use of human pluripotent cells or cells derived from human pluripotent cells may not commence without SCRO Committee	N/A	• This may have been an oversight when revising the definition of "covered stem cell line" ○ Replace "covered" with "human pluripotent"?

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review and approval in writing… §5(d)(2) Provide assurance that all *covered stem cell lines* have been acceptably derived. Applies to §5(f)(2) as well.		
§5(f) Research introducing *human pluripotent cells or cells differentiated from human pluripotent stem cell lines* into non-human animals…may not commence without SCRO Committee review and approval…	§100070(c) CIRM-funded *human subjects research*…with the aim to create…blastocysts or embryos, or use a covered stem cell line may not commence without *written notification*…	-CIRM includes written notification for CIRM-funded iPSC research to help keep track of collected somatic cells and the informed consent process in case subsequent derived cell lines are used in non-human animals • Does Committee want to revisit downstream research issues related to informed consent for somatic cells? • Currently this issue is not addressed as it falls under iPSC research
§5(f) Research introducing *human pluripotent cells or cells differentiated from human pluripotent stem cell lines* into non-human animals…may not commence without SCRO Committee review and approval…	§100070(c) CIRM-funded human subjects research… subsequent *introduction of derived covered stem cell lines in non-human animals* shall be reviewed in accordance with section (e).	- CDPH includes introduction of human pluripotent *cells* in animals - CIRM includes introduction of covered stem cell *lines* in animals • Is there a need to revise Guidelines or does deviation not present any operational difficulties for SCRO Committees?
§6(a)(2)(B) Donors of human gametes or embryos *did not receive valuable consideration for participation in research*.	§100080(a)(2)(B) For embryos *originally created* using in vitro fertilization *for reproductive purposes* and are no longer needed for this purpose, *"valuable consideration" does not include payments to original gamete donors* in excess of "permissible expenses."	-CDPH allows for cell lines derived from paid gamete donors if donation was initially made for reproductive purposes -CIRM allows for above per recently adopted §100080(a)(2)(B); however CIRM funds cannot be used for payment beyond permissible expenses to gamete donors (§100090(b))
§6(F) Be approved by CIRM in accordance with CCR, Title 17, Section 100081.	§100081 – discusses exemption petition	• Guidelines could include language that defers to CIRM for the addition of any future acceptably derived lines; however, this may be problematic if CIRM allows lines from other states as CPDH has statute indicating oocytes procured out

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		of state must follow CA statute (e.g. possible conflict with NY)
§7 – refers to deriving new covered stem cell lines	§100090 – uses Prop 71 cut-off date for embryos with regard to oocyte donor consent requirements	• Guidelines could include a statement encouraging researchers to incorporate informed consent into the research design so as to avoid "retrospective" consent
N/A	§100090(a)(4) – refers to somatic cells being used to develop cells for transplantation into humans (e.g. cord blood); donors need to be consented	• Guidelines do not address this issue; may not fit scope of Guidelines since iPSC research removed
N/A	§100100(B)(5) – refers to consent from mother of cord blood donor	• Guidelines do not address this issue; may not fit scope of Guidelines since iPSC research removed